Complete Summary

GUIDELINE TITLE

Chancroid. In: Sexually transmitted infections: UK national screening and testing quidelines.

BIBLIOGRAPHIC SOURCE(S)

Ison CA, Lewis DA. Chancroid. In: Ross J, Ison C, Carder C, Lewis D, Mercey D, Young H. Sexually transmitted infections: UK national screening and testing guidelines. London (UK): British Association for Sexual Health and HIV (BASHH); 2006 Aug. p. 47-51. [16 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chancroid

GUIDELINE CATEGORY

Diagnosis Evaluation Risk Assessment Screening

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Urology

INTENDED USERS

Advanced Practice Nurses Clinical Laboratory Personnel Nurses Physician Assistants Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

- To provide advice on what tests for chancroid are most appropriate in a United Kingdom genitourinary (GU) clinic setting (excluding human immunodeficiency virus [HIV]-infected patients)
- To provide a basis for audit
- To support clinics when bidding for additional resources to meet national standards

TARGET POPULATION

Individuals in the United Kingdom with or at risk for chancroid

INTERVENTIONS AND PRACTICES CONSIDERED

- 1. Testing of individuals with an ano-genital ulcer or a bubo in an individual at risk of acquiring chancroid
- 2. Isolation of causative agent, *Haemophilus ducreyi* (*H. ducreyi*), by direct plating using several culture media as specified
- 3. Direct detection of *H. ducreyi* by nucleic acid amplification
- 4. Microscopy and serology (considered, but not recommended)
- 5. Sampling from ano-genital ulcer material and bubo pus
- 6. Consideration of factors which alter tests recommended or sites tested
- 7. Repeat testing if ulceration persists after therapy for detection of drug resistance

MAJOR OUTCOMES CONSIDERED

Sensitivity and specificity of diagnostic tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

This guideline was obtained by searching the Medline database from 1980 up until November 2002 using the MeSH headings "chancroid, *Haemophilus ducreyi*, diagnosis." The United Kingdom National Guidelines for the management of chancroid were consulted. Centers for Disease Control and Prevention (CDC) sexually transmitted infection (STI) guidelines of 2002 were used as a source for expert consensus. The European guideline for the management of tropical genitoulcerative diseases was consulted. Key review papers were consulted.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

Ib: Evidence obtained from at least one randomised controlled trial

IIa: Evidence obtained from at least one well designed controlled study without randomisation

IIb: Evidence obtained from at least one other type of well designed quasi-experimental study

III: Evidence obtained from well designed non-experimental descriptive studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guidelines have been developed following the methodological framework of the Appraisal of Guidelines Research and Evaluation instrument (AGREE - adapted as described in *Int J STD and AIDS* 2004 15:297-305).

The extent to which the guideline represents the views of intended users has been addressed primarily by the authorship coming from the multidisciplinary membership of the Bacterial Special Interest Group (BSIG). As practising clinicians the authors were able to draw on their experience of applying the tests to symptomatic and asymptomatic patients, but it was not feasible to obtain formal input from representative patients.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grading of Recommendations

- A. Evidence at level Ia or Ib
- B. Evidence at level IIa, IIb, or III
- C. Evidence at level IV

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After drafting, other health care professionals and professional bodies in genitourinary (GU) medicine were asked to comment, the draft guidelines posted on the British Association for Sexual Health and HIV (BASHH) website for 3 months, and all comments reviewed before final publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the level of evidence (**I-IV**) and grade of recommendation (**A-C**) are provided at the end of the "Major Recommendations" field.

Testing, wherever possible, is recommended in all cases of ano-genital ulceration acquired overseas in areas of the world where chancroid is prevalent including

Africa, Asia, Latin America, parts of the USA and the Caribbean. The importance of asymptomatic carriage of *Haemophilus ducreyi* (*H. ducreyi*) is unclear.

Recommended Tests

Isolation of Causative Agent, H. ducreyi

- Culture of material obtained from the undermined edge of the ano-genital ulcer, after removing superficial pus with a cotton-tipped swab, that is plated directly onto culture medium and incubated at 33 degrees C, in high humidity with 5% carbon dioxide for a minimum of 48 to 72 hours. Transport media have been described but they have not been widely evaluated and in one study have shown little advantage over direct plating. Pus aspirate from inguinal buboes can also be cultured in the same way but the yield is lower than with ulcer-derived material.
- Different strains of *H. ducreyi* appear to grow preferentially on some culture media and so the use of more than one type of culture medium (described below) is recommended to give the greatest number of positives (sensitivity varies between 33% in low prevalence populations to 80%, in high prevalence populations (**Evidence level IIa, Grade of Recommendation B**). Addition of a selective agent, 3 mg/l vancomycin, is recommended. (**Evidence level III, Grade of Recommendation B**)
- Culture media include:
 - GC agar supplemented with 1% haemoglobin, 5% foetal calf serum, 1% IsoVitaleX and 3 mg/L vancomycin
 - Mueller-Hinton agar supplemented with 5% chocolatised horse blood,
 1% IsoVitaleX and 3 mg/l vancomycin
 - GC agar supplemented with 1% haemoglobin, 0.2% activated charcoal, 1% IsoVitaleX and 3 mg/l vancomycin

Direct Detection of H. ducreyi by Nucleic Acid Amplification

There are no commercial tests available but there are a number of laboratories which have described in house tests, some of which also amplify Treponema pallidum and herpes simplex virus (HSV). Molecular detection for H. ducreyi is available via local laboratories sending specimens to the Sexually Transmitted Bacteria Reference Laboratory (STBRL) at the Health Protection Agency (stbrl@hpa.org.uk). (Evidence level IIb, Grade of Recommendation B)

Microscopy

 Detection of sheets of Gram-negative cocco-bacilli has a low sensitivity and is not recommended as a diagnostic test. (Evidence level IV, Grade of Recommendation C)

Serology

 The detection of antibody to *H. ducreyi* as a marker of chancroid has been useful for epidemiological studies but has no role in direct patient management. (Evidence level III, Grade of Recommendation B)

Recommended Sites for Testing

- Ano-genital ulcer material
- Bubo pus

Factors Which Alter Tests Recommended or Sites Tested

Recent travel by an index patient with genital ulceration (or his/her sexual partner) to a part of the world where chancroid is endemic suggests that *H. ducreyi* infection should be considered as a cause of genital ulceration.

The presence of a bubo may require pus to be aspirated in addition to taking a sample of the ulcer material. The inability of the local laboratory to offer a diagnostic facility for *H. ducreyi* infection may make it impossible for the clinician to undertake a diagnostic test for chancroid. Due to the infrequency of requests the laboratory diagnosis for chancroid is often unavailable. In low prevalence populations, such as the UK, culture media is often produced in response to a typical clinical presentation, which has made it very difficult to maintain good quality control. There is no quality assurance programme for culture for *H. ducreyi* in the UK.

Risk Groups

- Men who have sex with men (no alteration to standard recommendation)
- Sex workers (no alteration to standard recommendation)

Other Groups

- 'Young' patients (no alteration to standard recommendation)
- Pregnant women (no alteration to standard recommendation)
- Women with a history of hysterectomy (no alteration to standard recommendation)

Recommendation for Frequency of Repeat Testing in an Asymptomatic Patient

- Testing should only be performed in the presence of an ano-genital ulcer or a bubo in an individual at risk of acquiring chancroid
- Screening asymptomatic patients is not recommended

Recommendation for Test of Cure

- A test of cure for chancroid is not recommended
- If ulceration persists after therapy for chancroid, patients should have a repeat chancroid culture performed to determine if a strain of *H. ducreyi* resistant to the prescribed antimicrobial is present

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised controlled trials

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Grading of Recommendations

- A. Evidence at level Ia or Ib
- B. Evidence at level IIa, IIb, or III
- C. Evidence at level IV

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate screening and diagnosis of chancroid

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

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• This guideline recommends the use of culture media and nucleic acid amplification technologies to diagnose *Haemophilus ducreyi* infection. However, these tests may not be routinely available in many laboratories.

 Staff in genitourinary medicine (GUM) clinics should liase closely with their laboratory staff to ensure that every effort is made to diagnose chancroid effectively.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

British Association for Sexual Health and HIV - Medical Specialty Society

SOURCE(S) OF FUNDING

No specific or external funding was sought or provided in the development of this guideline.

GUIDELINE COMMITTEE

Screening Guidelines Steering Committee Clinical Effectiveness Group (CEG)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Catherine A. Ison, Sexually Transmitted Bacteria Reference Laboratory, Health Protection Agency Centre for Infections, Colindale, London; David A. Lewis, Sexually Transmitted Infections Reference Centre, National Institute for Communicable Diseases, Johannesburg, South Africa

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

David Lewis and Catherine A. Ison have no potential conflicts of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from <u>British Association for Sexual Health and HIV Web Site</u>.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

Specifications for the development of UK guidelines on the management of sexually transmitted infections (STIs) and closely related conditions 2005.
 London (UK): British Association of Sexual Health and HIV (BASHH); 2005. 14 p. Electronic copies: Available in Portable Document Format (PDF) from the British Association for Sexual Health and HIV Web site.

Additionally, auditable outcome measures can be found in the <u>original guideline</u> document.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 20, 2008. The information was verified by the guideline developer on October 20, 2008.

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Date Modified: 11/10/2008

